TABLE 49

Determination of Respirable Dose, 1 mg/mL Fentanyl

Test	Method	Specification
Assay of Fentanyl in sublingual spray samples	Described in Example 17	Report Results
Determination of respirable dose in fentanyl sublingual spray by cascade impaction		Report Results

CI Run	Sample	Fentanyl (μg/dose)	Particle Size groupings	Groupings percent	Average Shot weight (mg)	Total Mass <9 μm (μg)	Respirable dose <9 μm (μg)
1	Globe	76.5694	≧9 μm	96.4	85.4	2.9	3.6
	Plate 0	0.5479					
	Plate 1	0.6228	9 μm >X ≧ 5.8 μm	0.8			
	Plate 2	0.4746	<5.8 μm	2.9			
	Filter	1.8149					
2	Globe	78.6941	≧9 μm	96.6	84.0	2.8	3.4
	Plate 0	0.6746					
	Plate 1	0.6217	9 μm > X ≧ 5.8 μm	0.8			
	Plate 2	0.5000	<5.8 μm	2.6			
	Filter	1.6740					
3	Globe	78.0529	≧9 μm	97.1	85.3	2.3	2.9
	Plate 0	0.5082					
	Plate 1	0.5429	9 μm > X ≧ 5.8 μm	0.7			
	Plate 2	0.4185	<5.8 μm	2.2			
	Filter	1.3596					
			Average percent respirable dose				3.3

Many other variations of the present invention will be apparent to those skilled in the art and are meant to be within the scope of the claims appended hereto, including but not limited to the particular unit dose or bi-dose devices and the particle size range of fentanyl produced, as well as other numerical parameters described in the examples, and any combination thereof.

What is claimed is:

1. A unit dose of a non-propellant sublingual fentanyl formulation comprising discrete liquid droplets of an effective amount of fentanyl and a pharmaceutically acceptable liquid carrier, wherein the sublingual fentanyl formulation comprises:

from about 0.1% to about 0.8% by weight of fentanyl or a pharmaceutically acceptable salt thereof;

from about 20% to about 60% by weight of ethanol; and

from about 4% to about 6% by weight of propylene glycol;

wherein after sublingual administration to a human, said sublingual fentanyl formulation provides a mean time to maximum plasma concentration (T_{max}) of fentanyl of from about 5 to about 120 minutes.

2. The unit dose of claim **1**, wherein said discrete liquid droplets have a size distribution of from about 10 μm to about 200 μm.

3. The unit dose of claim **1** wherein after sublingual administration to a human, the sublingual fentanyl formulation provides a mean time to maximum plasma concentration (T_{max}) of fentanyl of from about 10 to about 60 minutes.

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